DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

Re: Rozerem
Docket No.: 2006E-0040

MAY 19 2006

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 6,034,239, filed by Takeda Pharmaceutical Company, Ltd., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Rozerem, the human drug product claimed by the patent.

The total length of the regulatory review period for Rozerem is 2,224 days. Of this time, 1,920 days occurred during the testing phase and 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 22, 1999.

   The applicant claims May 5, 1999, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 1999, when the applicant was notified that the IND studies were allowed to proceed after being on clinical hold.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: September 22, 2004.

   FDA has verified the applicant's claim that the new drug application (NDA) for Rozerem (NDA 21-782) was initially submitted on September 22, 2004.

3. The date the application was approved: July 22, 2005.

   FDA has verified the applicant's claim that NDA 21-782 was approved on July 22, 2005.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Mark Chao, Ph.D., JD
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